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09/064,000	04/21/1998	JAMES P. ELIA	796-P-12	5311

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EXAMINER

KEMMERER, ELIZABETH

ART UNIT PAPER NUMBER

1646

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/064,000

**Applicant(s)**

ELIA, JAMES P.

**Examiner**

Elizabeth C. Kemmerer, Ph.D.

**Art Unit**

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2005.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 382-388 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 382-388 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 21 April 1998 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/21/04.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

## **SUPPLEMENTAL DETAILED ACTION**

### ***Status of Application, Amendments, And/Or Claims***

The petition filed on **11/5/2004** has been received and considered. The delay in acting upon the petition is regretted. Upon reconsideration, the *objection* to claims 382-388 for containing non-elected subject matter, has been *withdrawn*, in light of the following supplemental action. Thus the petition requesting the review of the previous objection to claims 382-388 is now moot.

The SUPPLEMENTAL DECLARATION OF ANDREW E. LORINCZ, M.D., received 15 November 2004, and the DECLARATION OF RICHARD HEUSER, M.D., received 22 November 2004, both submitted under 37 CFR 1.132, have been entered into the file. Neither declaration was referred to in the Appeal Brief regarding the rejection under 35 U.S.C. § 112, second paragraph (maintained below). Accordingly, the declarations will not be further commented upon in this Office Action. If Applicant believes that either (or both) of the declarations is pertinent to the rejections set forth in the instant Office Action, Applicant is invited to specifically point out how.

The fifth supplemental information disclosure statement (received 21 October 2004) has been considered.

The finality of the previous Office Action (mailed 18 October 2004) is withdrawn in view of the new grounds of rejection set forth below.

Claims 382-388 remain under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Withdrawn Objections And/Or Rejections***

The objection to claims 382-388 for informalities, as reading on non-elected subject matter, as set forth on p. 5 of the previous Office Action (mailed 18 October 2004) is *withdrawn* upon further consideration.

The rejection of claims 382-388 under 35 U.S.C. § 101 as set forth on p. 7 of the previous Office Action (mailed 18 October 2004) is *withdrawn* upon further consideration.

The rejection to claims 382-388 under 35 U.S.C. § 112, first paragraph, as set forth on p. 7 of the previous Office Action (mailed 18 October 2004) is *withdrawn* upon further consideration.

***35 U.S.C. § 112, Second Paragraph***

Claims 383 and 384 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The basis of this rejection is set forth at p. 5 of the Office Action mailed 03 June 2004.

Applicant's arguments (Appeal Brief, received 15 April 2005, pp. 9-12) have been fully considered but are not found to be persuasive for the following reasons.

Applicant argues that the specification clearly describes that the multifactorial and non-specific cells contemplated by the claims are stem cells and germinal cells, referring to p. 37, line 19 of the specification. Applicant argues that the specification

Art Unit: 1646

further describes such cells as being pluripotent at p. 50, lines 2-3 of the specification. Applicant urges that those skilled in the art are familiar with stem cells and understand that pluripotent stem cells are non-specialized cells that are capable of developing into endoderm, mesoderm or ectoderm, which in turn give rise to a variety of soft tissues and organs. Applicant refers to Example 15 of the specification as specifically describing using living stem cells harvested from bone marrow, blood or cell cultures. This has been fully considered but is not found to be persuasive. Page 37, line 19 of the specification states, "Multifactorial and nonspecific cells (**such as** stem cells and germinal cells)..." (emphasis added). Such an exemplary list does not constitute a definition setting forth the metes and bounds of the phrase. Page 50, lines 2-3 of the specification state, "The insertion of a multifactorial and nonspecific growth factor (or gene) is required. Such a growth factor is pluripotent, senses what body part..." This section establishes that **one of the features** of a "multifactorial and nonspecific" growth factor (wherein a "growth factor" is defined in the specification as encompassing cells) is that it is pluripotent. This still does not constitute a definition setting forth the metes and bounds of the phrase. Stem cells are at least pluripotent. However, the term "multifactorial and nonspecific cells" is not clearly limited to stem cells. Applicant's repeated referral to stem cells as exemplary of "multifactorial and nonspecific" cells does not clarify the metes and bounds of "multifactorial and nonspecific" cells. Claim 383 recites the limitation that the cells are multifactorial and nonspecific. Claim 384 depends from claim 383, assumedly further limiting claim 383, reciting that the multifactorial and nonspecific cells are stem cells. The crux of the issue is, what cells

Art Unit: 1646

other than stem cells can be considered multifactorial and nonspecific? If there are no such cells, then claim 384 does not further limit claim 383.

Applicant argues that the examiner's referral to the absence in the art of the term "multifactorial and nonspecific" being used to describe cells is not the standard for determining definiteness. Applicant refers to their own internet search as evidencing that those in the medical arts would readily understand that pluripotent stem cells are capable of forming multiple soft tissues including an artery and muscle and it is their "versatility and nonspecifically" that gives them the potential to have therapeutic application (applicant refers to Exhibit B of the Appeal Brief; however, the definition was found in Exhibit D). This has been fully considered but is not found to be persuasive. The definition in Exhibit D is somewhat problematic, since "nonspecifically" is an adverb and should not have been used to describe a noun ("cells"). Perhaps "nonspecificity" was intended. Regardless, the term was used to describe embryonic stem cells. Such cells can differentiate into any fully differentiated cell type (i.e., embryonic stem cells are omnipotent). Does "nonspecific" mean that the cell must be able to differentiate into **any** cell type (omnipotency) or just more than one cell type (pluripotency)? What abilities or features must a cell have in order for it to be termed a "multifactorial" cell? Again, the record simply does not clearly set forth the metes and bounds of the terms "multifactorial and nonspecific" as they are applied to describe a genus of cells.

Applicant argues that it is clear that they use the term "living organism" to describe a living thing, i.e., living matter, such as cells in general and living stem cells in particular. Applicant refers to Example 15 and pages 41-42 in support of such.

Art Unit: 1646

Applicant states that cells, such as stem cells, are living organisms, and that such is a fact that is so well understood by those skilled in the medical arts that the PTO should take Official Notice of such. Applicant refers to the petition (received 05 November 2004) which provides evidence from the NIH that cells are considered living organisms. Applicant refers to the NIH's definition of cell which states that all living organisms are made of one or more cells. This has been fully considered but is not found to be persuasive. There is no question that cells are living. However, they are not necessarily living **organisms**. Evidence has been brought forth by the examiner that the art defines a living organisms as capable of independent life (see previous Office Action for discussion of this). The new NIH definition of cell provided by Applicant only supports the examiner's interpretation. A living organism is made of living cells. A cell is part of a living organism. However, a cell is not necessarily a living organism itself. A skilled artisan would not consider a hematopoietic stem cell removed from a patient to be a separate living organism. It was isolated from a living organism. It is part of a living organism.

Applicant refers to the fifth supplemental information disclosure statement that crossed the final rejection in the mail. The references cited on this IDS have now been considered by the examiner. However, these references are found to support the rejection. The dictionary.net's definition of multifactorial is "involving or depending on several factors or causes (especially pertaining to a condition or disease resulting from the interaction of many genes)." This supports the rejection in that the term "multifactorial" is not used to describe cells. It is used to describe a cause (for example,

Art Unit: 1646

of the disease) or an effect (for example, of the genes). Similarly, the dictionary.net's definition of nonspecific is "not caused by a specific agent; used also of staining in making microscope slides; 'nonspecific enteritis' supports the rejection. "Nonspecific" is not used to describe cells. How can cells be "not caused by a specific agent?" The definition uses the term to describe causes (i.e., nonspecific enteritis is a disease caused by undefined factors).

For all of the reasons discussed above, the rejection is maintained.

### **New Rejections**

#### **35 U.S.C. § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 382-388 are rejected under 35 U.S.C. 102(b) as being anticipated by Lutjen et al. (1984, Nature 307:174-175).

Lutjen et al. disclose a method for producing a desired soft tissue in a body of a human patient comprising: (a) placing cells in said body of said human patient; (b) forming a bud in said body of said human patient; and (c) growing said desired soft tissue from said bud. See last paragraph of p. 174 through third paragraph of p. 175. Please note that the two-cell embryo that was implanted into the human patient constituted "cells" that were "placed" into the human patient's body as per step (a) of



Art Unit: 1646

claim 382. Also, please note that an embryo can be considered to read upon the elected species, a living organism. The cells used in the method of Lutjen et al. were multifactorial and non-specific according to the broadest reasonable interpretation of the limitation in claim 383, considering the cells gave rise to all of the cell types in the resulting healthy, full-term (38-week) fetus. The cells also comprised stem cells according to the broadest reasonable interpretation of this limitation as recited in claim 384, for the same reason. Regarding the recitation of "forming a bud" as recited in step (b) of claim 382, it is noted that normal growth of a fetus involves formation of numerous buds, including limb buds, for example. Regarding step (c) of claim 382, soft tissue, such as musculature and vasculature, inherently forms from these buds. Given that the method of Lutjen et al. resulted in the birth of a healthy baby boy, one skilled in the art would have concluded that the fetus underwent normal growth including bud and soft tissue formation. The method of Lutjen et al. also comprised growing a new artery (as recited in claims 385 and 386), in view of the fact that the resulting healthy, full-term fetus comprised new arteries. The method of Lutjen et al. also involved formation of soft tissue that comprised mesodermal cells and arteries (as recited in claims 387 and 388), in view of the fact that these tissues were comprised in the body of the healthy, full-term fetus.

**35 U.S.C. § 112, First Paragraph**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

Art Unit: 1646

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 382-388 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. The instant claims were submitted in the amendment received 19 August 2004. Said amendment did not point to specific parts of the specification for support for the new claim language. The claims recite forming a bud, and then growing desired soft tissue from the bud. The specification only uses the term "bud" in reference to tooth buds. Tooth buds do not form soft tissue, including arteries, as required by the claims.

### **Conclusion**

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (571) 272-0874. The examiner can normally be reached on Monday through Thursday, 7:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1646

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ECK

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